CardioVascular Group

Baxter Healthcare Corporation
17221 Red Hill Avenue (Irvine)
PO Box 11150
Santa Ana, CA USA 92711-1150
949.250.2500

Baxter

March 27, 2000

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services, Rm. 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re: Citizen Petition 00P-0498/CP 1
Request for Exemption for the Swan-Ganz Pacing Catheters and Probes
Amendment

This document provides additional information regarding Citizen Petition 00P-0498/CP1 for the Swan-Ganz Pacing catheters and probes.

Baxter submitted the Citizen Petition for these products based on the following:

- The Baxter Swan-Ganz Pacing catheters and probes are used with temporary pulse generators to provide temporary pacing, typically in urgent situations. Baxter does not manufacture temporary pulse generators or interfacing cables and, therefore, must rely on generators and interfacing cables manufactured by other companies.
- The Swan-Ganz Pacing catheters and probes are most often used with the Medtronic pulse generator, using an interfacing cable manufactured by Medtronic that accepts a single-pole pin lead configuration (see Attachment 1). Medtronic has indicated that they do not intend to modify the distal end of the cable that connects to our electrode

lead, thus preventing Baxter from making changes to the connectors that would comply with the performance standard (21 CFR 898) and still interface with the Medtronic cable.

- Modification of the Swan-Ganz Pacing catheters and probes to meet the performance standard would require development of an adaptor to connect the compliant, protected leads to the cable. In order to connect to the Medtronic cable, the adaptor would need a single-pole pin lead configuration at the proximal end. This would result in the same situation that is currently present with the Swan-Ganz Pacing products; detachment of the adaptor from the cable by the clinician would effectively convert the compliant, "safe" lead into a noncompliant, "unsafe" one (see Attachment 2).
- Creation of Swan-Ganz Pacing catheters and probes with compliant leads without availability of appropriate adaptors or cables to interface with the pulse generators could result in patient risk. Clinicians who rely on the use of these products - particularly in emergency situations - would not be able to connect the products to the pulse generator, thus presenting risk to the patient.

In discussions with Kent Berthold of the Office of Compliance, Baxter was informed that adaptors that connect with the Medtronic cable are available through Multicontact or Remington Medical, thus eliminating Baxter's requirement for an exemption. In light of this information, Baxter requests that a variance be granted for a period of 180 days to allow Baxter to convert the leads on the Pacing products to conform with the standard, to identify an adaptor that will interface with our compliant leads and the Medtronic cable or pulse generator, and to allow our customers time to acquire the interface cable/adaptor. The protected lead design (see Attachment 3) that Baxter has identified to meet the performance standard is per DIN 42802-2ST.

Baxter's request for the variance is based on preventing interruption of flow of these products to the field, which would present some patient risk. Baxter is the major supplier for some specialized Pacing products. Baxter is the only source for atrial or ventricular transluminal Pacing probes and atrial/ventricular thermodilution Pacing catheters. Baxter

is the market leader for flow-directed balloon Pacing catheters. The product sales for the Pacing products exceeded 35,000 units for 1999. Eliminating availability of this product would present patient risk.

All of the Pacing products are designed for easy use when administering emergency temporary pacing. Alternate pacing methods (e.g., pacing wire placement or use of non-flow directed catheters) are available but require more clinically skilled operators for electrode placement and result in increased patient risk. In the case of the transluminal probes, the patient would require an additional entrance site for temporary pacing and would suffer the trauma related to the maintenance of this extra site.

Thus, Baxter requests that a 180-day variance be granted to allow Baxter to meet the requirements of the performance standard and to allow customers to acquire appropriate adaptors without interrupting availability of the Pacing products.

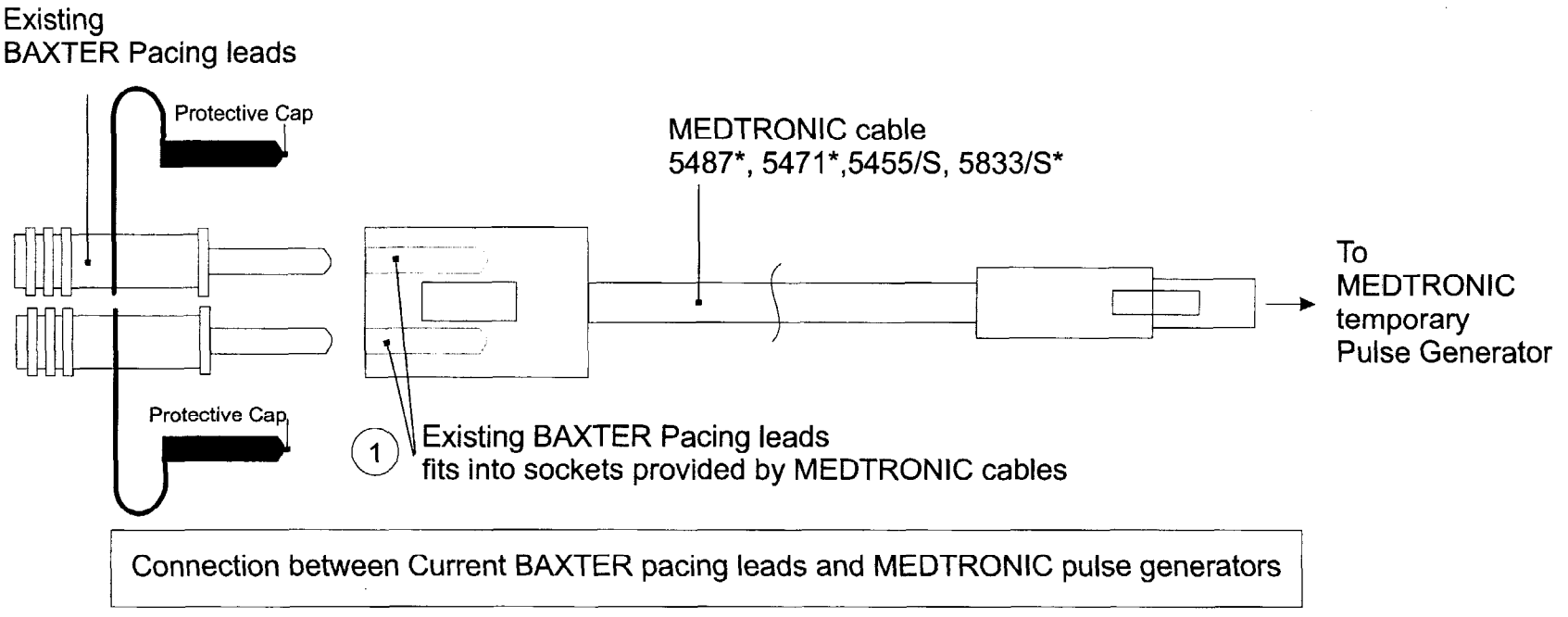
If you have any questions regarding the information provided in this amendment, please feel free to call me at (949) 250-2418.

Sincerely,

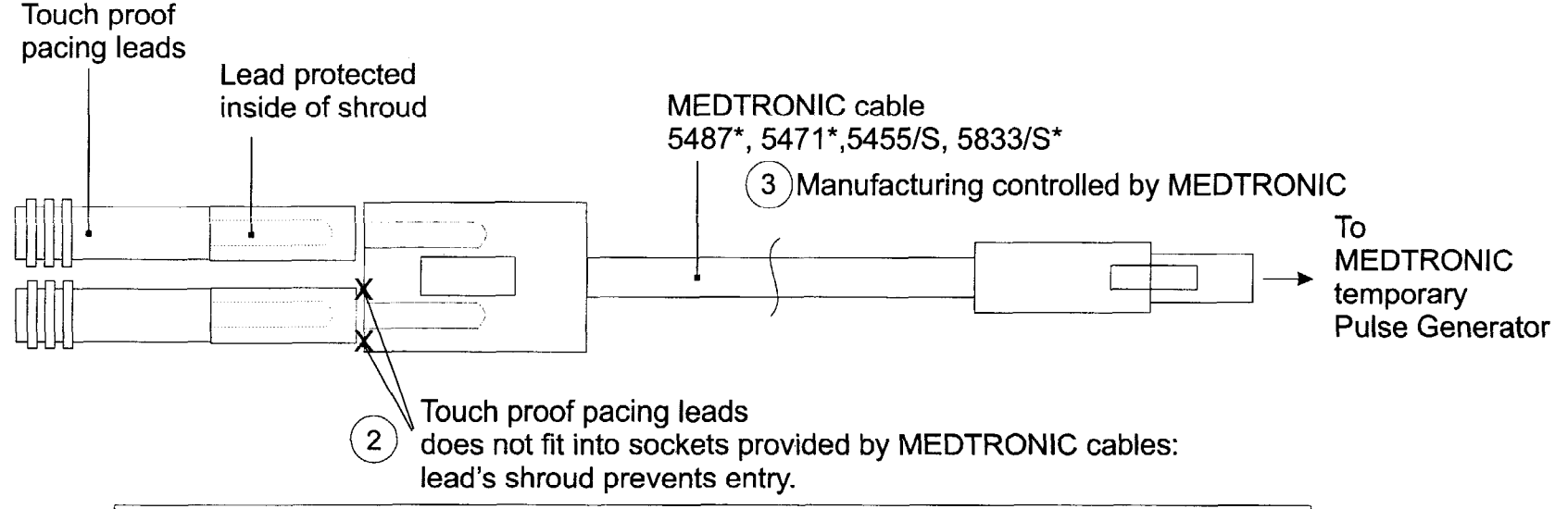
Paula A Torrianni

Paula A. Torrianni
Manager, Regulatory Affairs
CardioVascular Group

Attachment 1

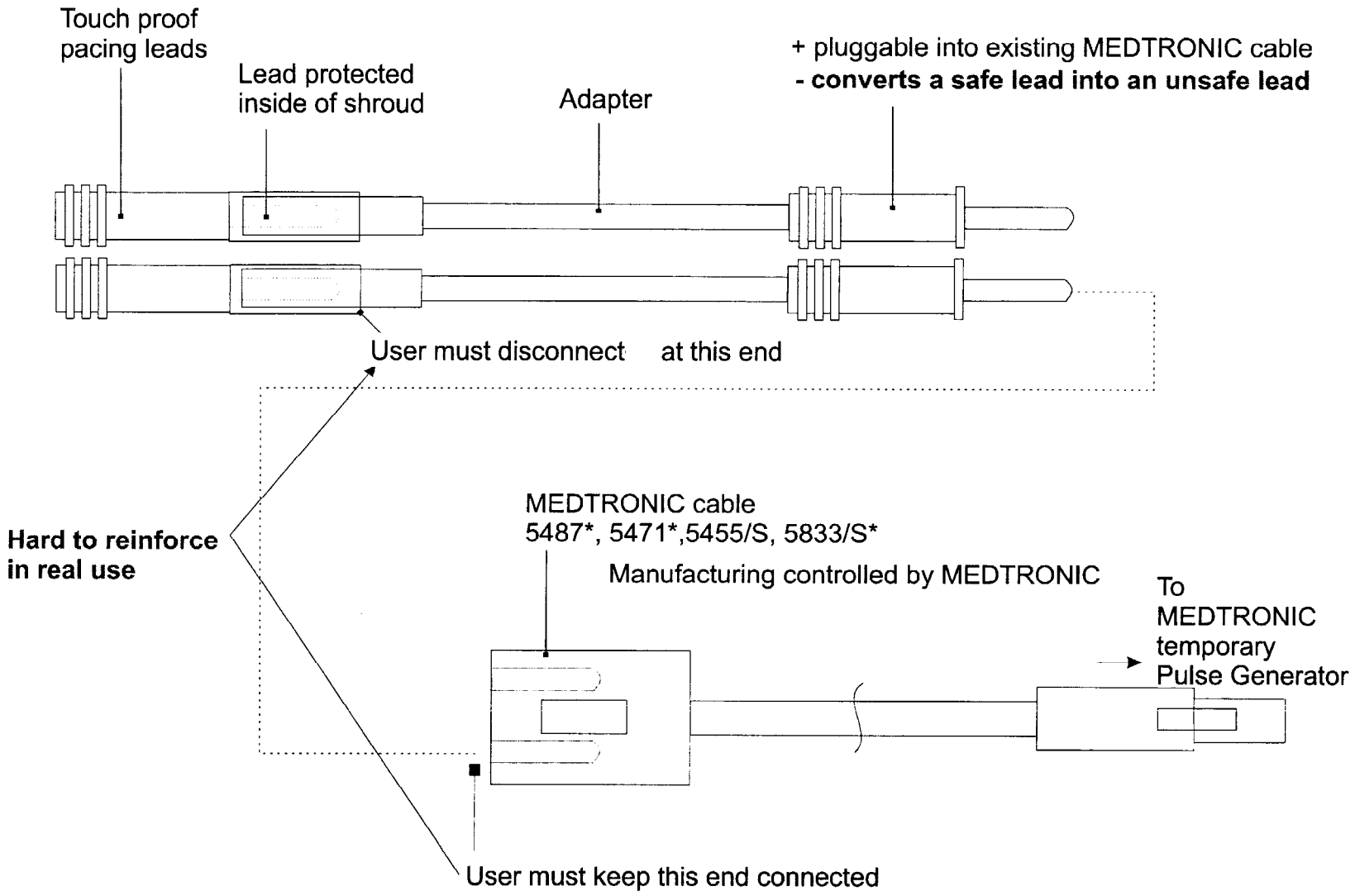


Connection between Current BAXTER pacing leads and MEDTRONIC pulse generators



Issue encountered in mating touch proof pacing leads to MEDTRONIC pulse generators

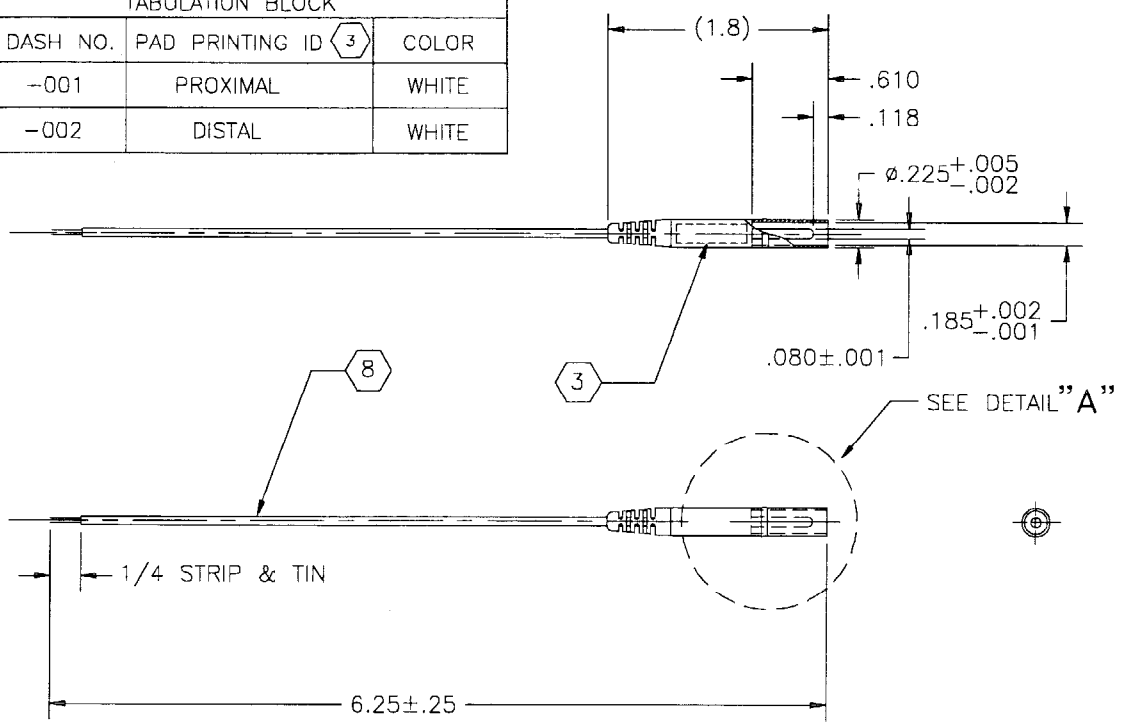
Attachment 2

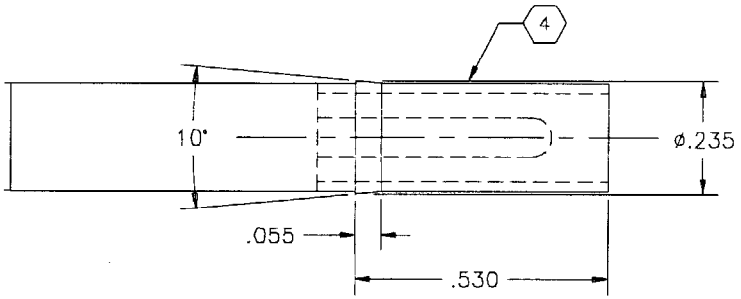


Issue encountered in using adapters to mate with existing MEDTRONIC pulse generator cables

Attachment 3

TABULATION BLOCK		
DASH NO.	PAD PRINTING ID ⟨3⟩	COLOR
-001	PROXIMAL	WHITE
-002	DISTAL	WHITE





DETAIL "A"
SCALE: 4X

DRAWING STATUS	PPNH ECN03701	PPH	PROD

REV LTR	CHANGE NO.	DESCRIPTION	APPROVAL DPTSPN	DATE	APPD	DATE
X1	ECN03701	PRE PROD NON HUMAN	FA	2/21/00	LF	3/1/00
X2	ECN03875	REV PER ECR	RM	3/16/00	KS	3/17/00

GENERAL NOTES: UNLESS OTHERWISE SPECIFIED

1. PRODUCT TO BE CLEAN, FREE FROM FLASHING AND GATE TO BE TRIMMED FLUSH.
2. MOLDED PORTION OF JACK TO BE COMPLETED WITHOUT DEFORMITIES AND BLACK IN COLOR.
3. ⟨3⟩ PRINT FONT IS TO BE 10 PT ARIAL BOLD. PRINT IS TO BE PAD PRINTED IN WHITE (2 PLACES).
4. ⟨4⟩ PIN PROTECTOR MATERIAL IS POLYPROPYLENE (P/N 030587) HOMOPOLYMER, ASTRYN 62K4-2C BLACK.
5. – NOTE OBSOLETE –
6. LEAD MUST WITHSTAND A 90 DEGREE FLEX TEST OF 1000 CYCLES AT STRAIN RELIEF. WITH AN 8 OZ. WEIGHT.
7. CHANGES TO PRODUCT MUST BE AUTHORIZED BY BAXTER HEALTHCARE CORP. AS GOVERNED IN CRITICAL COMPONENTS SUPPLIER AGREEMENT.
8. ⟨8⟩ MATERIAL: .08 COPPER WIRE.
9. CAN PURCHASE FROM LUDLOW TECHNICAL PRODUCTS.

CAD REFERENCE: PAPER/MODEL SPACE

ZONE	NO.
△ INSPECTION DIMENSIONS	

DASH NO. 001 002

TOLERANCES UNLESS OTHERWISE SPECIFIED

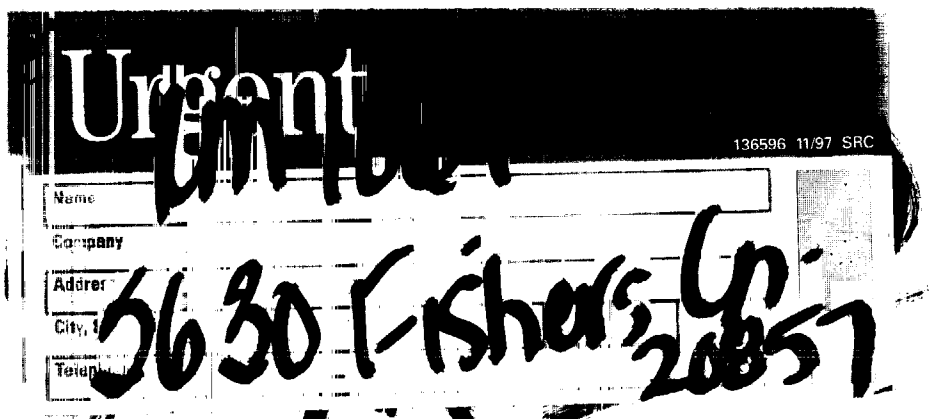
DIM. LIMITS	SURFACE FINISH 32
FRACTION ±1/32	⊥ .015 TIR
ONE PLACE ±.015	// .015 TIR
TWO PLACES ±.01	⌀ .005 TIR
THREE PLACES ±.005	BREAK ALL SHARP EDGES .01 X 45°
ANGULAR DIMS ±1°	ALL DIMENSIONS IN INCHES

Baxter
CARDIO VASCULAR GROUP
IRVINE, CALIF. 92614

TITLE: SAFETY PIN TAIL ASSEMBLY

DIVISION: CRITICAL CARE	AUTO CAD
APPD: LF	DATE: 3/1/00
DWN: FA	DATE: 2/21/00
SCALE: 1:1	SHT 1 OF 1
SIZE: B	DRAW NO.: 192014 REV: X2

BICVG LVPP



BAXTER HEALTHCARE CORP -CVC
BAXTER HEALTHCARE CORP.-CVC
1402 E. ALTON PARKWAY
IRVINE, CA 92606

SHIP DATE: 27MAR00
ACC # 108043473

ACTUAL WGT: 1 LBS SCALE

(714)250-[illegible] 1644

TO: DOCKETS MANAGEMENT BRANCH (301)000-0000
FOOD AND DRUG ADMINISTRATION
DEPT OF HEALTH & HUMAN SRVC, RM 1-23
12420 PARKLAWN DRIVE
ROCKVILLE MD 20857

4702 1890 2930 FedEx.

30

REF: RA INTIRA B./PAULA T. BUS DOCUMENTS

PRIORITY OVERNIGHT TUE

cad # 0016972 27MAR00

Deliver by:

TRK# 4702 1890 2930 FORM 0201 28MAR00

IAD AA

20857 -MD-US XA EDGA

153078-077 RIT 08/99

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